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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,935	KEMBLE ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,7 and 13-22* is/are pending in the application.

4a) Of the above claim(s) *9-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,7 and 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s) SBC 5/6/05

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 3, 7 and 13-22, is acknowledged and entered. The substitute sequence listing submitted on March 11, 2005 is also acknowledged and entered. Newly submitted claims 19-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 19-22 are drawn to a method of treatment comprising administering the cytomegalovirus (CMV) chimeric virus. These methods are classified separately, class 435, subclass 5. Further, the product can be used in a materially different method of use, such as detection of antibodies in a sample. A search for both the product and the method of its use is a serious burden. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Applicant's traversal of the restriction requirement has been fully considered but not found persuasive. Applicant argues that a single search would identify relevant art pertaining to a chimeric CMV virus, regardless of the nucleotide sequences of the various claimed chimerics. In response, a search for one chimeric would reveal pieces of information about the other chimerics, but not enough information to make a patentability determination because the sequences would be incomplete. A search for all the chimeras would be a serious burden since none of them share the same genetic composition (see specification, Table 2. Therefore, the restriction is deemed proper and made FINAL. Claims 3, 7, 13-18 are pending and under

examination. Claims 19-22 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Objections

3. Claim 3 is objected to for a minor informality. "CMV" should be spelled out at its first occurrence, since the acronym "CMV" also refers to other viruses, such as cucumber mosaic virus.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 14, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to Chimera I which comprises various sequences having at least 90% sequence identity to the Towne and Toledo genomes. Specifically, the chimeric has the following genetic composition:

- Polynucleotides having at least 90% identity to a high-passage Towne genome from nucleotides 1-3799, 81,647-170,499, and 205,803 to the S-term; and

- Polynucleotides at least 90% identity to a Toledo genome from nucleotides 15,750-67,568 and 175,069-203,136; and
- Polynucleotides comprising a crossover region from nucleotides 3,800-15,749, 67-81,646 and 170500-175,068.

The claims are drawn to a CMV construct comprising polynucleotides having at least 90% sequence identity with a particular disclosed sequence. The claims do not require that the polypeptide possess any particular biological activity besides being immunogenic, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that are defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. If one considers all of the possible modifications that can be made to a nucleotide sequence within 90% identity, the number of resulting polynucleotides is enormous. For example, a polynucleotide that has 90% sequence identity to the Towne genome from nucleotides 81,647 to 170,499 could be one of millions of possibilities. A substitution or deletion at any point of the 88,852 nucleotide bases

with any of the four nucleotide bases yields countless variations. Applicant's examples have only demonstrated possession of a few species of an extremely large genus of 90% sequence identity.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. Therefore, only the polynucleotides of Chimera I (100% identity) were in Applicant's possession at the time of invention. The full breadth of the claims do not meet the written description provision of 35 U.S.C. §112, first paragraph.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3, 7, and 13-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The claims are drawn to a Chimera for which no sequences have been provided with which to reference the claimed nucleotides. Which sequences in the sequence listing correspond to the sequences in the claims? The sequences of the Towne and Toledo genomes that were used in this invention are not disclosed in full in this application.
- Chimera I, according to the specification in Table 2 has a fixed sequence. The claims that are drawn to chimeric CMVs that have 90% identity seemingly conflict with the fixed sequence of the Chimera of claims 3 and 7. The metes and bounds of the claims cannot be determined without a clearer definition. Correction and clarification is required.
- The claims recite, "a high passage Towne genome". This term is unclear because "high passage" is relative terminology, subject to individual interpretation. Since Applicant's specification shows that the Towne genome was passaged over 125 times, such language would more clearly define a "high passage" Towne genome. Correction is required.

Conclusion

6. No claim is allowed. For background information, Chimera I is an attenuated chimeric CMV comprising Towne DNA and Toledo DNA. The Towne strain was isolated from the urine of a congenitally infected infant, passaged over 125 times and found to be an avirulent virus.

Due to the extensive passaging, the Towne strain is overattenuated and does not induce a protective immune response against human CMV challenge, as does the natural human immune response to CMV. The Toledo strain was also isolated from the same infant, passaged 5 times and found to remain virulent. Vaccine candidates are generated by replacing genetic elements of the Towne strain with homologous portions of the virulent Toledo strain (specification, page 39). Table 2 discloses the genetic composition of Chimera I. The prior art of record does not teach or suggest the chimerics having the specific sequences of those disclosed in Table 2 of the specification for Chimera I. The closest prior art of record is US 5,721,354, which teaches the sequences of a Towne and Toledo genome, however, chimerics having the configuration of Applicant's Chimera I are not taught or suggested. Also of record is Spaete *et al.* (Science Symposium in Tucson, AZ, 1998, cited in the IDS of 12/8/04) which discloses Towne/Toledo chimerics without disclosing specifics such as points of insertion/deletion/recombination. Without these details, it would not have been obvious to make the claimed Chimera I.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
May 6, 2005